



Food and Drug Administration
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Accuray Incorporated
% Mr. Keith Picker
Regulatory Affairs Specialist
1209 Deming Way
MADISON WI 53717

April 14, 2015

Re: K143269
Trade/Device Name: Delivery Analysis
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ, IYE
Dated: April 8, 2015
Received: March 6, 2015

Dear Mr. Picker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. Behind the signature, there is a faint, large watermark of the letters "FDA" in a stylized font.

for

Robert Ochs, PhD
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143269

Device Name

Delivery Analysis

Indications for Use (Describe)

Delivery Analysis is indicated for making:

- Quantitative comparisons of planned and measured MLC fluence sinograms
- Quantitative comparisons of the planned dose distribution to the dose distribution calculated based upon the measured MLC fluence sinogram
- Quantitative comparisons of the delivered detector sinograms from one fraction to another

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 7 510(k) Summary

Applicant

Accuray Incorporated
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Contact: Keith Picker
Date Prepared: November 4, 2014
Date Revised: April 8, 2015

Device Identification

Device Name: Delivery Analysis
Trade & Brand Names: Delivery Analysis
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged particle radiation therapy system
Regulatory Class: Class II
Primary Product Code: MUJ
Secondary Product Code: IYE

Predicate Device

Dosimetry Check Version 4 Release 1 (K132605)

Device Description

Delivery Analysis is a software tool that runs on a standalone workstation used to compare radiation therapy pre-treatment and measured in-treatment data with information describing the planned radiation treatment delivery. The pre-treatment assessment tools provide a means to confirm whether the multi-leaf collimator (MLC) has performed according to the treatment plan and evaluate any differences in MLC performance that may affect the treatment delivery. The in-treatment assessment tools allow comparison of the current radiation treatment fraction as delivered with previous fractions to evaluate the consistency of the treatment delivery with particular sensitivity to variations in patient setup and anatomy.

Delivery Analysis is a computer-based analysis tool for viewing plan and treatment delivery system data, making quantitative comparisons among data sets, trending specific metrics associated with deliveries, and calculating the dose implications for some

measured quantities from the treatment delivery system. Delivery Analysis is designed for use with the TomoTherapy Treatment System last cleared under 510(k) number K121934. Delivery Analysis uses the radiation fields that are measured with the TomoTherapy fan-line detector array to provide both theoretical calculations and direct comparisons of raw data on a fraction per fraction basis.

Delivery Analysis™ is compatible with any TomoTherapy® System. Prerequisites are:

- Software version 2.0.5 (TomoTherapy H™-Series and Tomo HD™; 5.0.5 for TomoTherapy Hi·Art™) or higher
- DICOM Export Data Services Package (standard with all H™ Series systems; available as an upgrade option for other systems)

Further, Delivery Analysis will not work with any systems that do not meet the above stated prerequisites.

Intended Use

Delivery Analysis is intended to be used to assess the measured MLC fluence sinogram with respect to the planned MLC fluence sinogram. The assessment augments, but does not replace, the pre-treatment delivery quality assurance assessments outlined in the TomoTherapy Treatment System Delivery Quality Assurance Guide.

Delivery Analysis is intended to be used to assess the dose calculations resulting from using the measured MLC fluence sinogram with respect to the dose calculation resulting from using the original planned MLC fluence sinogram. The assessment augments, but does not replace, the pre-treatment delivery quality assurance assessments outlined in the TomoTherapy Treatment System Delivery Quality Assurance Guide.

Delivery Analysis is intended to be used to quantify the consistency of the post-patient detector signal from fraction to fraction over the course of a patient's radiation therapy treatment. Variations in the consistency of the post-patient detector signal can be an indication of patient anatomy change or alignment inconsistency. The determination of the degree of inconsistency that is clinically relevant and any subsequent alterations to the patient treatment are the sole responsibility and discretion of the user.

Delivery Analysis does not diagnose disease, recommend treatment regimens, or quantify treatment effectiveness. It is not intended for diagnostic use.

Indications for Use

Delivery Analysis is indicated for making:

- Quantitative comparisons of planned and measured MLC fluence sinograms
- Quantitative comparisons of the planned dose distribution to the dose distribution calculated based upon the measured MLC fluence sinogram
- Quantitative comparisons of the delivered detector sinograms from one fraction to another

While the indications for use for Delivery Analysis are stated differently from those of the predicate, the differences are not critical to the intended use of the devices: the analysis, review, and assessment of radiation fields measured by the TomoTherapy fan-line detector array. Both devices provide the same types of data analysis and data comparisons. Neither Delivery Analysis nor the predicate device provide any conclusions regarding the results of the data analysis, nor do they provide criteria to be used for interpreting the results. Experienced clinicians evaluate the data from their patient-specific radiation treatment plans in accordance with their medical training and clinical judgment.

Technological Characteristics

Delivery Analysis and the predicate device employ the same fundamental scientific principles, and have substantially equivalent technological characteristics and principles of operation.

Both Delivery Analysis and the predicate device use the same types of data to provide the same types of information to the user. Where there are technological differences in implementation, and in the way the information is presented to the user, those differences do not raise different questions of safety or effectiveness. Further, neither device is a required accessory to any system that provides therapy to patients.

A table comparing the predicate cleared on K132605 and Delivery Analysis is presented below:

Product Characteristics or Features	Predicate Device Dosimetry Check Version 4 release 1 (K132605)	Subject Device Delivery Analysis
Type of Therapy Assessed		
Photon Therapy	Yes	Yes
Electron Therapy	No	No
C-arm-based RT Systems	Yes	No
Ring-based RT System (TomoTherapy)	Yes	Yes
Pre-Treatment Assessment		
Ability to use TomoTherapy System detector data from a pre-treatment plan without the patient in the treatment bore	Yes	Yes
Compute dose in planning CT, and compare computed dose to planned dose	Yes	Yes
Provides dose difference or gamma analysis	Yes	Yes
In-Treatment Assessment		
Ability to use TomoTherapy System exit detector data from a treatment delivery	Yes	Yes

Product Characteristics or Features	Predicate Device Dosimetry Check Version 4 release 1 (K132605)	Subject Device Delivery Analysis
Type of Therapy Assessed		
Photon Therapy	Yes	Yes
Electron Therapy	No	No
C-arm-based RT Systems	Yes	No
Ring-based RT System (TomoTherapy)	Yes	Yes
Pre-Treatment Assessment		
On a treatment by treatment basis, provide a comparison of delivered dose or fluence to planned or previously delivered dose or fluence	Yes*	Yes*
Provide dose/fluence difference or gamma analysis	Yes	Yes
*Both devices provide an in-treatment assessment on a treatment-by-treatment basis, using the same detector data as the basis for the comparisons. A minor technological difference is that the predicate device processes the raw data to present results based upon dose, whereas Delivery Analysis presents results based upon the raw data.		

Performance Data

Results of verification and validation testing confirm that Delivery Analysis conforms to design specifications and meets the needs of the intended users. No clinical tests were required to establish substantial equivalence. The performance data demonstrate that Delivery Analysis is as safe and effective, and performs as well as the predicate device.

Conclusion

Delivery Analysis is substantially equivalent to the predicate device. The intended use, major technological characteristics, and the principles of operation of Delivery Analysis are substantially equivalent to those of the predicate device. Minor differences do not raise different questions of safety and effectiveness of Delivery Analysis in comparison to the predicate device. Further, performance data demonstrate that Delivery Analysis is as safe and effective, and performs as well as the predicate device. Accordingly, Delivery Analysis is substantially equivalent to the predicate device.